

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MISSOURI  
SOUTHEASTERN DIVISION**

**UNITED STATES ex rel. CAIRNS,  
et al.,**

**Plaintiffs,**

**v.**

**D. S. MEDICAL, L.L.C., et al.,**

**Defendants,**

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**Case No. 1:12 CV 00004 AGF**

**DEFENDANTS' TRIAL BRIEF**

Introduction

Defendants respectfully submit that, on a number of grounds, this case could very likely be ripe for a directed verdict. Defendants do not make such a statement lightly. Maybe the Government has evidence of which Defendants are unaware, but based on multiple developments in this case since 2014, Defendants' constant refrain that the Government lacked substantive evidence is concretely being realized. The Government's total failure to find a qualified expert for any issue in this case is extremely telling. Not only did the Government fail to find an expert to support its claim of lack of medical necessity (after telling the Court for two years it had one), but it also never found an expert to testify that Dr. Fonn's rent was less than fair market value. Then, as to the one and only expert the Government did eventually produce in this case, the Government has since withdrawn that witness, following Defendants' *Daubert* motion noting not only the witness' lack of expertise, but more importantly, her having simply eliminated data which flatly contradicted her conclusion and which she could not explain. More significant than its failure to procure expert testimony, Defendants learned just last week that Todd Stanaford, who was trumpeted at one point as the star witness and who the Government

has definitively asserted negotiated the Verticor contract with Ms. Seeger, was informed that the Government was not going to call him as a witness. Finally, the Government concedes that if it is unable to use its summary evidence related to alleged Medicare/Medicaid claims (because, among other reasons, it failed to produce the underlying material, contrary to Rule 1006), it “could seriously jeopardize the government in its ability to prove its case.” Doc. 285, p. 11.

### The Government’s Claims and Defendants’ Defenses

#### I. False Claims Act

Counts I, II and III of the Complaint in Intervention all depend upon alleged violations of the False Claims Act, 31 U.S.C. §§3729-33 (the “FCA”). For Counts I and II, the Government must prove that the Defendants knowingly submitted or caused to be submitted false claims for payment or approval to Medicare or Medicaid. For Count III, the Government must prove that the Defendants conspired to defraud the United States by having false or fraudulent claims allowed or paid. For all three counts, the Government must also prove materiality.

##### A. Submission of Claims

As an initial matter, Defendants note that the Government may be unable to establish, through admissible evidence, that either St. Francis Medical Center or Midwest Neurosurgeons submitted any of the claims upon which the Government bases its allegations that the Defendants violated the False Claims Act. The Government has acknowledged as much in its response to other motions in this case. *See, e.g.*, United States’ Reply in Support of its Motion for Leave to File Supplemental Declarations (Doc. 285), at p. 11 (“the presentation of claims is essential to proof in an FCA case . . . [denying the government’s motion] could seriously jeopardize the government in its ability to prove its case”).

Respectfully, the Government failed to comply with Rule 1006 regarding its claims data. The Government has admitted that it has only produced spreadsheets containing limited self-selected categories of information obtained from a governmental contractor (in the case of Medicare) and from the Missouri Medicaid Fraud Unit. During his 30(b)(6) testimony, Agent Minden unequivocally testified he did not include all the data STARS had related to Dr. Fonn's surgeries, but rather hand selected that data he included from a "menu" of categories. Minden 30(b)(6) Depo., pages 14, 21, 39-40. In its most recent filing, Doc. # 285, the Government acknowledges that there are hundreds of data fields, but that it only provided Defendants with what it unilaterally determined "was most relevant to the matters at issue and those upon which it intended to rely." *Id.* p. 8. Moreover, the claim that the "most relevant" data fields were selected (which is actually irrelevant under a Rule 1006 analysis) is belied by Agent Minden's own testimony that 1) he was not even familiar with all the fields to be able to select the "most relevant" – "my point is simply that there could be other fields that I'm not aware of or I'm not particularly familiar with that reflect information." Minden 30(b)(6) Depo., p. 45 –and 2) his testimony that he really did not know why he picked all the data fields he selected.<sup>1</sup>

#### **B. Claims Must be False**

Even if the Government could prove that claims were submitted, the Government will be unable to prove that the claims were false. Here, the only basis upon which the Government alleges that any claims constitute false claims is the Government's allegation that the Defendants

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**<sup>1</sup> Q: And why did you ask for that claim that column?**

A: I don't know specifically. Routinely when I'm pulling these - I have - I do at an ad hoc basis I'll look through the list of fields, because there's it's not always the same.

**Q: There's a whole bunch of fields you could have chosen?**

A: I could have - I choose ones that I know I need and often I'll pick ones out that I'm not certain what their significance is to determine if I can figure out what their significance is I can only assume this, this was one of those that I thought I included just to see if it made any difference to me.  
Minden Depo., p. 21.

violated the Anti-Kickback Statute, 42 U.S.C. §1320a-7b(b) (the “AKS”). Accordingly, any claims submitted to the Government can be false only (a) if the claimant expressly certified the absence of any AKS violation; or (b) if the claimant impliedly certified the absence of an AKS violation; or (c) if, pursuant to 42 U.S.C. §1320a-7b(g), for claims submitted on or after March 23, 2010 the claim became a false claim if it *resulted from* a violation of the AKS.<sup>2</sup>

1. Express or Implied Certification.

In this case, there will be no evidence of any express certification by SFMC of compliance with the AKS. With respect to implied certification, the Government will not be able to meet the legal standard needed to make a submissible case. *See generally Universal Health v. United States ex rel. Escobar*, 136 S.Ct. 1989 (2016). The *Escobar* decision completely changed the landscape as to the applicability of an implied certification theory. Under *Escobar*, two conditions must be satisfied. First, the claim must do more than simply demand payment. *Id.* at 2001. It must also make a specific representation about the goods or services provided. *Id.* Second, the claimant’s failure to disclose the violation of a statutory, regulatory or contractual requirement must make the specific representation a misleading “half-truth”. *Id.* The Government will not be able to satisfy these conditions.

Accordingly, only claims submitted on or after March 23, 2010 should be at issue in this case, and the only possible basis for the allegations of violations of the FCA, with respect to such claims, is the allegation that the Defendants violated the AKS.<sup>3</sup> For the reasons discussed below, however, the Government will be unable to establish any AKS violations.

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<sup>2</sup> The statute declaring claims to be false if they resulted from an AKS violation did not take effect until March 23, 2010. Accordingly, no claims allegedly submitted in this case prior to that date can be false claims unless the Government proves that such claims expressly or impliedly certified compliance with the AKS.

<sup>3</sup> “In addition to the penalties provided for in this section or section 1320a-7a of this title, a claim that includes items or services *resulting from* a violation of this section constitutes a false or fraudulent claim for

## 2. Anti-Kickback Statute

In order to establish a violation of the AKS, the Government must prove that a defendant (a) knowingly and willfully, (b) solicited or received (or offered or paid) remuneration, (c) in return for (or in order to induce) the ordering, arranging for or recommending the purchasing or ordering of any good for which payment may be made under a Federal health care program. *See* 42 U.S.C. § 1320a-7b(b). In this case, the Government alleges two general types of kickbacks. First, the Government alleges that Defendants Seeger and DS Medical (“DSM”) offered or paid, and Defendant Fonn solicited or received, remuneration in connection with Dr. Fonn’s specification to the hospital of the spinal implants he desired to use. Second, the Government alleges that all Defendants solicited or received, or conspired to solicit or receive, kickbacks from spinal manufacturers in exchange for, or to induce, a hospital to purchase, order or recommend spinal implant devices.

The Government, however, cannot prove<sup>4</sup> an AKS-violation under either theory.

### a. Alleged Kickbacks from Seeger/DSM to Fonn

The Government will be unable to establish remuneration going from Deborah Seeger or DSM to Dr. Fonn; moreover, even if the Government could show remuneration, it cannot show that the remuneration was offered to induce, or that the remuneration was received in return for,

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purposes of subchapter III of chapter 37 of title 31.” 42 U.S.C. §1320a-7b(g) (emphasis added). Importantly, the statute does *not* provide that all AKS violations are automatically violations of the FCA but only that the one element of falsehood is established. And the statute does not address materiality at all.

<sup>4</sup> For a discussion of the Defendants’ position as to the appropriate burden of proof to which the Government should be held in connection with its allegations of AKS violations, *see infra*. at pp. 15-16.

Dr. Fonn's use of spinal implants supplied by companies represented by DSM,<sup>5</sup> and it cannot show that any defendant acted willfully as that term is used in the AKS.

As a matter of fact and law, Deborah Seeger and DSM did not pay remuneration to Dr. Fonn. Significantly, the Government does not claim to have any evidence of direct cash payments from Ms. Seeger or DSM to Dr. Fonn. Instead, the Government's claims of remuneration fall into two categories: (a) items related to the house on Helmsdale owned by Ms. Seeger in which she and Dr. Fonn have resided since October 2009 (the "Helmsdale House"), and (b) other expenditures unrelated to the Helmsdale House.

With respect to the Helmsdale House, there can be no remuneration because Dr. Fonn, at all relevant times, paid a substantial amount in rent (specifically, \$2,500 per month, later increased to \$2,500 per month plus one-half of the cost of utilities) to Ms. Seeger (his fiancé) to live with her. In other words, the Government's astounding theory here is that the party allegedly *receiving* the kickback paid more than \$2,500 per month to the party allegedly paying the kickback! Consequently, Dr. Fonn's living in the house can be remuneration only *if the Government proves* that the \$2,500 plus utilities was substantially less than the value of what Dr. Fonn received, *viz.*, the ability to live in the house, *see Health Dimensions Rehabilitation, Inc. v. RehabCare Group, Inc.*, 4:2012-cv-848 2013 WL 4666338 at p. 5 (E.D.Mo. Aug. 30, 2013) and only if Defendants acted willfully, that is, with criminal intent. But, in discovery, the Government has provided no evidence which it will be able to present to a jury to support a finding that the rent paid was substantially less than the value received. In contrast, the Defendants, though having no burden to do so, will show that the amount paid by Dr. Fonn was

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<sup>5</sup> For a discussion as to whether the AKS requires that the primary purpose of the remuneration be the inducing of referrals, or whether it is sufficient if referrals constitute just one purpose of the remuneration, *see infra* at p. 16.

intended by Defendants' attorney to exceed a fair value such that Dr. Fonn's living in the house simply cannot constitute illegal remuneration. Defendants respectfully contend that, at the conclusion of the Government's case, the Court will agree that this theory (Ms. Seeger "allowing" her fiancé to live with her constitutes illegal remuneration) cannot go to the jury.<sup>6</sup>

With respect to the non-Helmsdale House items alleged by the Government to constitute unlawful remuneration, the evidence will establish that, as to each specific item, Dr. Fonn did not use or benefit from the item. Defendants respectfully contend that there will be insufficient evidence to send this theory to the jury as well.

Even were the Government able to show remuneration, the Government is unable to establish a second element of the AKS, namely, that the remuneration was offered/paid and solicited/received in order to induce and in return for the referral of business. Ms. Seeger and Dr. Fonn have been engaged for a long time. They live together. They are in a loving, committed relationship. It borders on the absurd to think that Dr. Fonn, who made significantly more money at all relevant times than did Ms. Seeger, would have chosen which implants to use so that he could obtain things from Ms. Seeger. And it borders on the absurd to think that Ms. Seeger would not have shared her life and her possessions with her fiancée but for his referral of business to DSM. Whether the law requires that the primary purpose of the remuneration be the

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<sup>6</sup> Even if the Government's theory with respect to the Helmsdale House had any viability, it could only apply to a subset of claims in this case. First, Ms. Seeger and Dr. Fonn did not move into the residence until October 2009. Defendants believe the Government does not - and cannot - have any quarrel with the amount of rent at the time the couple began residing there. Under the Government's theory, only substantial improvements to the property could cause the amount of rent to be insufficient. No substantial post-move-in improvements occurred until December 2009. But then the rent did increase, with Dr. Fonn taking on responsibility for half of the utilities. If the Government is going to claim that Dr. Fonn received remuneration from Ms. Seeger by paying insufficient rent to live in the Helmsdale House, then it must fall upon the Government, as the party bearing the burden of proof, to establish at what point in time the amount of the rent allegedly fell short of the value enjoyed by Dr. Fonn. Any claims allegedly submitted before that point in time could not have resulted from (or even been related to) an AKS violation and, therefore, could not be false claims.

referrals, or that only one purpose of the remuneration need be the referrals, the Government will not be able to prevail under either test.

Moreover, the Government will not be able to show that any of the Defendants acted willfully, the mental state required by the AKS. To establish that a defendant "willfully" violated the Anti-Kickback Statute, the government must prove that the defendant knew his conduct was wrongful or unlawful and acted with the intent to do something that the law forbids, that is, with criminal intent. *See* Manual of Model Criminal Jury Instructions for the District Courts of the Eighth Circuit (2014 ed.) 6.42.1320, 7.02; *United States v. Yielding*, 657 F.3d 688, 708 (8<sup>th</sup> Cir. 2011), *cert. denied*, 132 S.Ct. 1777 (2012); *United States v. Jain*, 93 F.3d 436, 440-41 (8<sup>th</sup> Cir. 1996); *United States ex rel. Jamison v. McKesson Corp.*, 900 F.Supp.2d 683, 702 (N.D.Miss. 2012). In this case, the Government will not be able to prove that any of the Defendants knew their conduct was wrongful or unlawful, or that any of the Defendants acted with the intent to violate the law. On the contrary, the evidence will show that, prior to engaging in the transactions giving rise to this action, the Defendants sought and obtained legal advice concerning the legality of their contemplated conduct. Defendants will prove, though the burden is not theirs, that the fact that the Defendants sought legal counsel negates any notion that they had the intent to break the law. Defendants will prove that their intent was to *comply with* the law, that they sought out an attorney's help to direct them as to how to do so, and that they worked very hard to follow his dictates.

The Court should be aware that Defendants are *not* invoking an advice-of-counsel defense, but are instead introducing their interactions with an attorney for the purpose of negating the Government's contention that they acted willfully. "Circumstances like the advice of counsel . . . can negate willfulness, but they do not constitute an absolute defense." *United*



*States v. Civella*, 666 F.2d 1122, 1126 (8<sup>th</sup> Cir. 1981). *See also United States v. Taglione*, 546 F.2d 194, 200-01 (5<sup>th</sup> Cir. 1977) (trial court erroneously excluded testimony of an attorney as to a telephone conversation between defendant and the attorney, which was probative of defendant's state of mind during the course of the alleged crime; appellate court distinguished proffered evidence from situation where defendant "is asserting reliance on advice of counsel as a defense"); *cf. United States v. Frame*, 236 Fed.Appx. 15, 18-19 (5<sup>th</sup> Cir. 2007) (defendant may present to the jury, to negate criminal intent, his defense that he relied on advice of counsel, even absent an advice of counsel instruction).

Courts have recognized the different ways in which the term "advice of counsel" has been used. "[T]he 'thrust of [the defense] is that the defendant, on the basis of counsel's advice, believed his conduct to be lawful and thus could not be found to have had unlawful intent.'" *United States v. Gorski*, 36 F.Supp.3d 256, 267 (D.Mass. 2014) (quoting *United States v. Beech-Nut Nutrition Corp.*, 871 F.2d 1181, 1194 (2d Cir. 1989)). "More specifically, the term 'advice of counsel defense' has a specific, relatively narrow meaning and a broader, somewhat more colloquial meaning." *Id.* at 267. The Court in *Gorski* described the "narrow" advice-of-counsel defense as one where the defendant could "have the jury instructed" as to the defense if the defendant established certain prerequisites. *Id.* In contrast, "[t]he second, and broader, sense of the term arises when a criminal defendant seeks to introduce evidence, or argue to the jury, that the advice or involvement of a lawyer tended to negate his *mens rea*, even if the defendant could not establish all the elements of the formal defense." *Id.* at 268. In the case at bar, Defendants will be introducing evidence as to their interactions with attorneys pursuant to what the *Gorski* Court called the "second, and broader" sense of the term "advice of counsel". Defendants will

not be presenting a narrow, formal advice of counsel defense, nor will they ask the Court for a specific jury instruction as to advice of counsel.

b. Alleged Kickbacks from Spinal Implant Manufacturers

The Government's AKS claims with respect to manufacturers of spinal implants will fare no better. The only possible remuneration which the manufacturers could have paid in this case were the commission payments made by them to DSM.<sup>7</sup> But there will be no evidence that either defendant ever demanded any particular commission rate or percentage from the two companies alleged to be the payers of kickbacks in Count II or from any of the non-identified companies with respect to Count III. For Count II, the evidence will establish that Amedica determined the initial commission to be paid to DSM, and then, approximately a year later, offered a higher commission rate to DSM. The initial commission (30%) was set by Amedica, and Ms. Seeger did not ask for anything higher. (Indeed, the first DSM – Amedica contract is not even mentioned in the Government's Complaint.) With respect to the increase of the commission rate to 50%, despite an allegation to the contrary in the Government's Complaint, discovery has disclosed no evidence to support a contention that the Defendants demanded the higher commission to DSM in exchange for Dr. Fonn's use of Amedica's products.<sup>8</sup> As for Verticor, the evidence will be that DSM did not even know what commission that company would pay until it was determined, as a result of discussions and negotiations (as to which

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<sup>7</sup> This was the only alleged remuneration identified by the Government in response to Defendants' specific interrogatory requesting identification of any illegal remuneration provided by spinal manufacturers.

<sup>8</sup> In fact, in the Plaintiff's final response to Defendants' Request for Admission # 15, which requested the Government to admit that "[n]either Dr. Fonn nor Ms. Seeger demanded or insisted upon a 50% commission from Amedica," the Government responded that it was "unable to admit or deny" – clearly demonstrating it does not have evidence of any such demand.

neither Ms. Seeger nor DSM was a party) between Jon Wait<sup>9</sup> and Verticor, that the commission would be 45%, subsequently raised to 50%, again as a result of negotiations between Wait and Verticor and not involving Ms. Seeger or DSM.<sup>10</sup> With respect to all other, unnamed manufacturers, the Government will have no evidence of any illegal remuneration paid by them to any Defendant, and the evidence will establish that all commission rates paid by any manufacturer for whom DSM served as a distributor fell within the usual and customary range for commissions paid by manufacturers of similar size and place in the industry. While at first blush a 50% commission might sound excessive, not only will the evidence show it is not uncommon, but a Government witness has already testified that his company was paying all its distributors commissions of 50% to 55% (yet only paid Ms. Seeger 40%).

Moreover, the Government's claims under the commissions-were-kickbacks theory have no viability unless the Government can show that money paid by the manufacturers to DSM induced Dr. Fonn to use implants he would not otherwise have used and that Ms. Seeger shared the proceeds of the commissions with Dr. Fonn. *See* United States' Opposition to Defendants' Motions to Dismiss Based on Rule 12(b)(6) and Rule 9(b) (Doc. 80) at p. 14. In this case, the evidence will be undisputed that neither Deborah Seeger nor DSM had any decision-making authority as to what implants would be purchased by the hospital for use in Dr. Fonn's surgeries. That decision was made solely by Dr. Fonn. Accordingly, no kickbacks exist unless money paid by the manufacturers went to him. But, all the commission payments were made to DSM. And, for the reasons discussed above, *see supra* at pp. 6-7, the evidence will not establish that any of

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<sup>9</sup> Jon Wait was an Amedica sales manager who was helping Ms. Seeger get DSM off the ground and who negotiated, without Ms. Seeger's involvement, DSM's initial contract with Verticor.

<sup>10</sup> Tellingly, Defendant Sonjay Fonn's First Request for Admissions # 17 requested the Government to admit that "Todd Stanaford [Verticor's CEO] never told the Government that Ms. Seeger or Dr. Fonn suggested that Verticor could not get Dr. Fonn's business without a 50% commission payment." The Government responded that it **"does not know why Verticor elected to pay Ms. Seeger a 50% commission"** and was "unable to admit or deny" this request.

the manufacturers' payments went from Deborah Seeger or DSM to Dr. Fonn. Thus, there are no kickbacks that can support the Government's theory under Count II or III. Stated differently, there was no remuneration to Dr. Fonn, so there can be no AKS violation under either of these counts.

Finally, as is the case with respect to the alleged kickbacks from Seeger and DSM to Fonn, here too the Government will be utterly unable to show that any Defendant acted willfully, that is, with the intent to violate the law. DSM's attorneys were involved, without fail, every time DSM entered into a contractual relationship with a manufacturer of spinal implants – including discussions of commission. The intent of Ms. Seeger and DSM in involving counsel to review and advise on these contracts was to make sure that, in all of her dealings with the manufacturers, she was complying with the law. The Defendants clearly did not willfully violate the AKS in this case.

c. “But For” Requirement of 42 U.S.C §1320a-7b(g)

Defendants contend that, under *Burrage v. United States*, 134 S.Ct. 881, 889 (2014), the AKS requires the Government to show that the alleged false claims in this case “result[ed] from” the alleged AKS violation, *i.e.*, that but for the alleged kickbacks, Dr. Fonn would have performed different procedures, performed them in a different manner, or utilized different implants. *See* Docs 68, and 84. Defendants further contend that the Government will be unable to make this showing.

C. Materiality

Materiality is a “rigorous” and “demanding” standard, and requires the Government to show the violation had an actual impact on the Government, not merely that the Government could have denied the claim. *Escobar*, 136 S.Ct. at 2002-04. It is not enough that the violation

might have tended to influence the Government; there must be evidence of actual influence.

Defendants submit that the Government will be unable to show materiality in this case.

## II. Common Law Claims (Counts IV and V)

Defendants respectfully suggest that the Government's common law claims (mistake of fact and unjust enrichment), set forth in Counts IV and V of the Government's Complaint in Intervention, should not be submitted to the jury. If the jury finds in favor of Defendants on Counts I, II and III, then those findings will necessarily establish the absence of any payment by mistake or unjust enrichment. *See, e.g., LaCroix v. U.S. Bank, N.A.*, No. 11-3236, 2012 WL 2357602 at p. 7 (D. Minn. June 20, 2012). And, in any event, the resort to equitable claims is inappropriate where the Government has an adequate legal remedy, the FCA. *See United States v. Job Resources for the Disabled*, No. 97 C 3904, 2000 WL 562444 at p.4 (N.D. Ill. May 9, 2000); *United States v. Hydroaire, Inc.*, No. 94 C 4414, 1995 WL 86733 at p. 6 (N.D. Ill. Feb. 27, 1995).

### Damages

The FCA provides that, if the Government establishes a violation, then its damages include "3 times the amount of damages which the Government sustains *because of* the act." 31 USC §3729(a)(1) (emphasis added). In this case, the Government's position is that, if it prevails, damages should be calculated simply as three times the amount paid out by the Government with respect to any claim determined to be false.

A number of obstacles, however, will confront the Government in establishing its damages at all and in supporting the damages calculation for which it will argue.

First, Defendants respectfully contend that the Government simply will not be able to establish, with admissible evidence, not only whether any specific claims were submitted to the

Government at all, *see infra* at pp. 2-3, but also the dollar amounts allegedly paid out by the Government with respect to any such claims. Defendants have discussed this issue at length in other filings with the Court. *See, e.g.*, Defendants' Response in Opposition to the Government's Motion for Leave to File Supplemental Declarations (Doc. 280); Defendants' Surreply in Opposition to Motion for Leave to File Supplemental Declarations (Exhibit 1 to Doc. 287). Defendants will also be filing a Motion in Limine as to the Government's Spreadsheets Reflecting Alleged Claims Filed by and Payments to Either Midwest Neurosurgeons or Saint Francis Medical Center.

Second, this Court should not permit the Government to attempt to include in its damage calculation any expenses unrelated to the alleged AKS violation, *i.e.*, amounts for services unrelated to the surgeries performed by Dr. Fonn. In a previous case before this Court, *United States ex rel. Health Dimensions Rehabilitations v. RehabCare Group*, 4:12-cv-00848-AGF, the Defendants filed a motion urging this exact position, and this Court granted that motion. Defendants will be filing herein a similar Motion in Limine to Exclude from Any Damage Calculation Expenses Unrelated to Surgeries. Defendants will not state here the arguments to be included in that motion, except to say that when the Government pays a claim in connection with a patient operated on by Dr. Fonn, the payment includes amounts for services beyond the surgery. As the party with the burden of proof trying to establish its damages, it is up to the Government to cull out from its alleged damages the amounts attributable to the costs of such unrelated services.

Finally, Defendants contend that the Government's damages should be based upon its actual losses and that the value of the goods or services actually provided should be deducted from the damages calculation. Defendants will be filing a Motion to Calculate Damages Based

on the Government's Actual Losses, which will discuss this argument in detail. Defendants recognize that this Court rejected a similar argument in *RehabCare Group, supra*, but respectfully urge this Court to reconsider its previous ruling in light of the intervening decision in *Burrage v. United States*, 134 S.Ct. 881 (2014), which sheds light on the proper interpretation of the AKS, 42 U.S.C. §1320a-7b(g) ("a claim that includes items or services *resulting from* a violation of this section constitutes a false or fraudulent claim") (emphasis added) and the FCA, 31 U.S.C. §3729(a)(1) (person who violates FCA must pay "3 times the amount of damages which the Governments sustains *because of* the act of that person") (emphasis added).

### Other Issues

#### I. Burden of Proof for Anti-Kickback Statute Allegations

On September 17, 2014, Defendants filed herein Defendants' Motion Regarding Standard of Proof (Doc. 66), along with a memorandum in support (Doc. 67). In that motion Defendants argued that because (a) the Government cannot successfully prosecute an action under the FCA unless the Government proves a violation of the AKS, and (b) the AKS is strictly a criminal statute, then the Government should be required to prove the AKS violation beyond a reasonable doubt. Stated differently, in this case there is no FCA violation absent an AKS violation, and there is no AKS violation unless it is determined by a fact-finder that a crime was committed. At least where the resulting punishment is punitive a fact-finder cannot find that a crime was committed unless the Government proves the commission of the crime beyond a reasonable doubt.<sup>11</sup> This Court denied the motion on November 16, 2014 (Doc. 87).

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<sup>11</sup> In fact, the title to the statute which makes any violation of the AKS a false statement under the FCA is "42 U.S.Code § 1320a-7b, Criminal penalties for acts involving Federal health care programs."

In their memorandum supporting the motion, Defendants set forth in full the legal authorities which, Defendants contend, compelled the granting of the motion, including but not limited to *United States v. Shapleigh*, 54 F. 126 (8<sup>th</sup> Cir. 1893). Defendants will not restate here all of their arguments. Defendants will be submitting proposed jury instructions that require the Government to prove any AKS violation beyond a reasonable doubt, while retaining the preponderance of the evidence standard for the remaining elements of the Government's FCA claims.

II. Anti-Kickback Statute: Primary Purpose or One Purpose

The Court has already construed the AKS to require only that one purpose of any remuneration be to induce referrals, rejecting Defendants' arguments that the jury should be required to find that referrals were the primary purpose of the remuneration. *See* Doc. 277 at p. 9. Defendants respectfully advise the Court that, in order to preserve the point for possible appeal, Defendants will be submitting proposed jury instructions consistent with the primary-purpose test.

III. The Government's Witnesses as to Comparative Utilization of Spinal Implants During Spinal Surgery Were Not Properly Disclosed as Experts

On February 9, 2017, Defendants filed their Joint Motion in Limine Regarding Evidence of Lack of Medical Necessity (Doc. 240). After the Government filed its memorandum in opposition (Doc. 242) and Defendants replied (Doc. 243), the Court ruled on the motion on April 7, 2017 (Doc. 248). In its ruling the Court noted that the Government represented that it would not intend to prove at trial that any surgeries or implants in this case were medically unnecessary; based on that representation, the Court stated that it would not permit the Government "to argue a 'lack of medical necessity.'" (Doc. 248 at p. 4 n.2). However, in resolving what the Court characterized as a "somewhat close question," (*id.* at p. 5), the Court stated that it would allow



the Government to present evidence of “comparative usage” by Dr. Fonn compared with his peers.

Defendants will be filing a motion in limine explaining how, even under the Court’s previous ruling generally leaving open to the Government the possibility of showing some kind of comparative usage, the Government’s lack of appropriate and admissible evidence on the issue should eliminate comparative usage as an issue to be discussed at trial. Specifically, for the Government to present testimony as to *comparative utilization of spinal implants during spinal surgery*, the witness will of necessity need to rely on “specialized knowledge” thus requiring application of Rule 702.<sup>12</sup> However, the Government did not identify any Rule 702 witnesses.

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<sup>12</sup> It is also highly improbable that any current witness will have the necessary expertise to so testify.

Respectfully submitted,

Dated: September 25, 2017

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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that on September 25, 2017, a copy of the foregoing was filed electronically with the Clerk of Court to be served by operation of the Court's electronic filing system on all counsel of record.

/S/ Sanford J. Boxerman